NOV 2 6 2002

GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201

K023178

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
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Summary prepared: 17 September 2002

Identification of Product: Digital Fluoroscopic Imaging System
Classification Name: Stationary X-ray System
Manufacturer: GE Medical Systems Europe
283, rue de la Minière
78530 Buc Cedex, France

Distributed by: GE Medical Systems, Milwaukee, WI

Marketed Devices: The Digital Fluoroscopic Imaging System is substantially equivalent to the currently marketed cardiographic system **LCV+ Version 2** so-called **Innova 2000** introduced in 2000 (K993037) that complies with the same or equivalent standards. The collimator used (Siemens model # 0468264 G052G) was introduced in the Siemens angiographic device **Sireskop** (version SX ou SD cleared under K971452) in 1997. The Review station used so-called **Advantage Workstation 4.1** was introduced in 2000 (K020483).

Device Description: The **Digital Fluoroscopic Imaging System** is designed to perform fluoroscopic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodide scintillator. The resulting digital image can be sent through a Fiber Channel link to an acquisition equipment then to network (in using DICOM) for applications such as post-processing, printing, viewing and archiving. **Digital Fluoroscopic Imaging System** consists of an angiographic monoplane positioner, a vascular table, an X-RAY system and a digital detector.

Materials: All construction and materials are compliant with UL 187 for the existing parts of the product and with UL 2601 for the new parts.

Design: There are hardware and software redundancies to prevent from single point failures that could cause unintended motion.

Energy Source: 480 VAC 50/60Hz.

Indications for Use: The **Digital Fluoroscopic Imaging System** is indicated for use in generating fluoroscopic images of human anatomy for diagnostic and intervention angiography procedures. It is intended to replace fluoroscopic images obtained through the image intensifier technology. This device is not intended for mammography applications.

Comparison with Predicate: The **41 cm Digital Fluoroscopic Imaging System** is substantially equivalent to the 20 cm Fluoroscopic system so-called Innova 2000 (Originally Cleared as the LCV+ Version 2; K993037).

Summary of Studies:

- **A clinical comparison study:** 6 radiologists from 3 hospitals: Saint-Luke's Hosp. (Bethlehem, Pennsylvania - US), Saint-Francis Hospital, (Peoria, Illinois – US); Centre Paris Nord (Sarcelles – France) compared digital images recorded on Innova 2000 and Innova 4100 from 11 pairs of patient sequences and found that the digital images from the Innova 4100 had equivalent image diagnostic capability.
- **A non-comparative clinical evaluation** of the Large Field of View (40 cm) image diagnostic capability has been conducted by the same group of radiologists as well.
- **A non-comparative clinical evaluation of fluoroscopy** in all FOV conducted in real time of the clinical procedures by three radiologists of Saint-Luke's.

Conclusions: GE considers the **41 cm Digital Fluoroscopic Imaging System** to be equivalent with the predicate device. The **41 cm Digital Fluoroscopic Imaging System** provides fluoroscopic images that result in equivalent diagnostic capabilities than the 20 cm images. The potential hazards, e.g., wrong measurements and misdiagnosis, are controlled by a risk management plan including:

- A hazard identification
- A risk evaluation
- A Software Development and Validation Process

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems, Inc
P.O. Box 414, W-709
MILWAUKEE WI 53201

Re: K023178
Trade/Device Name: Innova 4100
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 MQB and IZI
Dated: September 20, 2002
Received: September 23, 2002

Dear Dr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K023178

Device Name: **Digital Fluoroscopic Imaging System – Innova 4100**

Indications for Use

The **Digital Fluoroscopic Imaging System** is indicated for use in diagnostic and interventional angiographic procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventionnal procedures. This device is not intended for mammography applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023178